

## REMARKS

Applicant's remarks concerning the cited art contained in the amendment filed on August 13, 2002 are relevant to the present rejections and are incorporated herein by reference. A summary of those remarks is attached at the end of this document for the Examiner's reference. The present remarks are supplementary and are intended to be read in light of the remarks contained in the previous amendment.

The examiner has objected to the drawings as not showing every feature of the invention specified in the claims. Specifically, the claims recite a longitudinal axis which is not shown in the drawings. The examiner has suggested that this objection can be overcome by canceling the term "longitudinal axis" from the claims. Accordingly, the claims have been amended to remove this language from the claims. The objection to the drawings should be withdrawn.

The examiner indicates that the application does not meet the requirements for priority in that the original specification in the current application is not identical to that in the parent application. Applicant submits that the specification as filed should be treated as a substitute specification as provided for in 37 CFR section 1.53 (d)(5) "Any new specification filed with the request for an application under this paragraph will not be considered part of the original application papers, but will be treated as a substitute specification in accordance with § 1.125." A marked up copy of the specification has been provided showing the differences between the current specification and the parent specification. Applicant is not aware of any rule or law requiring the action set forth in paragraph 4 of the Office Action (namely surrendering a claim of priority or modifying the claim to a continuation in part) and the applicant requests the authority under which the examiner makes this requirement.

Unless the examiner can provide some authority for the requirement concerning priority, applicant will maintain the claim of priority. If the additional disclosure is considered “new matter” then it would be proper to require the removal of the additional disclosure from the specification and to reject those claims referring to this “new matter” under 35 USC 112 first paragraph – written description requirement. Accordingly, the issue seems to be whether the additional disclosure constitutes “new matter”. As suggested by the MPEP section 2163.06 “information contained in any one of the specification, claims or drawings of the application may be added to any other part of the application without introducing new matter.” The additional disclosure describes features that are shown in the drawings. The drawings are the same as the drawings presented in the parent application. Accordingly, the drawings as filed support the additional disclosure such that the additional disclosure is not “new matter”. The objection with respect to the claim of priority should thus be withdrawn.

The examiner has rejected claims under 35 USC 112, second paragraph in paragraphs 6, 7 and 8 of the Office Action. The rejections concerning the use of “longitudinal axis” have been addressed as described above with respect to the drawings by canceling the terminology in question from the claims. The lack of antecedent basis rejections have been addressed also. The rejections set forth in paragraphs 6-8 should be withdrawn.

The Examiner has made several § 112 rejections. The first rejection concerns a misunderstanding on the Examiner’s part concerning applicant’s arguments concerning the Sylvanowicz reference, perhaps due to a lack of clarity on the part of applicant’s attorney. With respect to the Sylvanowicz, the argument is not that the claimed curve must start at the distal tip of the catheter. Rather, the argument is that in Sylvanowicz the reference itself states that “a straight distal segment 62” extends from the curved portion 60. We are not forced to guess in

*plain & simple*

Sylvanowicz what constitutes the distal segment—the reference itself tells us. Moreover, the reference itself tells us that the distal segment 62 is “straight”. By its plain language, therefore, Sylvanowicz cannot meet the relevant limitations of the present claims. The § 112 rejection on this ground was, at best, based upon a misunderstanding and should be withdrawn.

With respect to the § 112 rejection found in paragraph 9 of the Office action, the Examiner states “The examiner does not find in the specification as originally filed, a time period or medical procedure associated with figures 15 and 15b, which provide the sole disclosure to that which is being claimed now.” Page 7 of the present specification describes Fig. 15 as a “side elevation of the transformable catheter of Fig. 13 illustrating a third achievable shape.” This statement makes all the disclosure of Fig. 13 relevant to Fig. 15. And Fig. 13 is clearly directed to the “transformable catheter of the present invention”. For example, on page 16, it states, “The transformable catheter of the present invention is capable of achieving entire separate families of shapes. As shown in Fig. 13 . . . .” Fig. 13, and hence Fig. 15, are, therefore, directed to “the transformable catheter of the present invention”. That catheter is described on page 10 as follows (with respect to Figs. 2A—2D and 3A—3C):

“In fact Figs. 2A—2D and 3A—3C all illustrate some of the multitude of different catheter shapes which may be **formed in the body, during a medical procedure**, using the present invention. It should be realized that these shapes are merely illustrative and that with suitable manipulation of the sheath and relative movement between the sheath and the catheter, a great number of additional catheter configurations may be achieved.”

The manipulation of the sheath and relative movement between the sheath and the catheter referred to in this passage is clearly the same manipulation and movement described in

connection with Figs. 13 and 15. The Examiner's position, therefore that there is a § 112 problem in connection with Figs. 15 and 15B is, therefore, baseless.

Fig. 15B is described as "a diagrammatic representation of a family of shapes similar to that of Fig. 15." And on page 17 of the present specification, it states: "Again, a whole family of these "out of plane" curves can be achieved as desired by the user by curving the sheath more or less and exposing more or less of the inner catheter or element." This passage clearly contemplates the formation of these different shapes by the user in the human body. And the passage recited above clearly indicates that the catheter of the present invention is used in medical procedures and that the shapes are changed while in the human body.

The examiner has rejected claims 1-7 under 35 USC section 101 as being drawn to non-statutory subject matter. The claims have been amended such that the identified structure must be capable of performing the identified function. See *In Re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976). As such the claims are no longer drawn to both a method and an apparatus and the rejection under 35 USC section 101 should be withdrawn.

Turning to the rejections under § 102 and § 103, the first rejection is based upon Sylvanowicz. In this rejection, the Examiner has failed to take into account the limitations (described in the previous amendment) that distinguish Sylvanowicz. It is plainly improper for the Examiner to ignore limitations relating to the placement of the various curves in order to find the present invention in Sylvanowicz. As described in detail in the previous amendment, Sylvanowicz simply does not show or suggest the present invention.

The Examiner also takes the position that the Sylvanowicz catheter is capable of assuming the claimed "out of plane configuration". This assertion is contrary to the teaching of

Sylvanowicz. In col. 7 of Sylvanowicz it describes the process of reorienting the catheter to change from the left coronary ostium to the right coronary ostium. At lines 26-30 it specifies:

“Such withdrawal shifts the location of the primary curve proximally along the length of the catheter which causes a repositioning of the **distal portion of the inner catheter** so that it **points toward the right coronary ostium.**” (Emphasis added).

That is, Sylvanowicz teaches that the inner catheter always points toward the desired ostia.

Similarly, it teaches that the distal portion of the sheath also point toward the desired ostia. For example, in col. 7, lines 26-49, Sylvanowicz specifies:

“By withdrawing the sheath proximally to reposition the primary curve, the **distal segment 62 is reoriented and points toward the right coronary ostium.**”

Note that Sylvanowicz talks about portions and segments pointing toward the ostia, not just the tips of the catheter and sheath. Since these portions and segments are confined with respect to one another, and since they are specified as pointing to the same location, it is geometrically required that they be in the same plane. The Examiner’s hypothetical construction is simply inconsistent with the express teaching of Sylvanowicz and is in error. This rejection should be withdrawn for this reason as well.

The additional references cited by the Examiner do not add anything, since they cannot be read to overcome the express disclosure of Sylvanowicz.

With respect to the rejection based upon Costella or D’Amelio, the D’Amelio et al. reference was discussed extensively in the prior amendment. Costella adds nothing to D’Amelio et al. The Examiner cites Costella as teaching an “inner element probe and outer guide insertion tube, each of which has a two plane bending assembly”. However, the portion of Costella cited

for this feature, col. 8, lines 30-34, actually says, “using articulating means capable of moving one or both of the probe and guide insertion tube in four directions also would lend the device to many different applications.” The Examiner apparently takes this passage to mean that the probe and guide insertion tube should be manipulated by the unspecified “articulating means” independently **at the same time**. That is not, however, what Costella says. Rather, the reference states that articulating means can be used to move “one” of the probe or guide insertion tube, or “both”, presumably together. For example, why would Costella refer to the possibility of using a probe or a guide tube that could be manipulated in four directions if Costella contemplated using the interaction of those components to make various shapes? With the present invention, all the shapes desired can be achieved with two curved (or curvable) elements, each of which bends in only one plane. Costella clearly does not contemplate the present invention since it contemplates that probes and guides tube movable in four directions are necessary for certain applications. This passage of Costella, cited by the Examiner, therefore teaches away from the present invention.

Moreover, there is absolutely no disclosure in Costella of an out-of-plane configuration as required by these claims. Costella appears to teach that if you need to point in a particular direction, you simply rotate the probe or guide tube in that direction and bend the probe or guide tube if necessary. Nowhere does Costella even hint that by bending the probe and the guide tubes at right angles one can obtain an out-of-plane configuration. Nor is there any indication in Costella that such a configuration would be desirable. (Note that D’Amelio taught to avoid such configurations, so the silence of Costella must be read to adopt the teaching of D’Amelio in this regard). Therefore, the out-of-plane apparatus and method claims of the present invention are not shown or suggested by Costella. It is only the applicant’s present disclosure that enables the

Examiner to make this logical leap. That is an improper use of hindsight. Moreover, several of these claims require fixing the inner medical element translationally with respect to the catheter tube. Costella, however, has no such translational fixing, so these claims are allowable for this reason as well.

The rejection on Petruzzi is fundamentally flawed for the reasons set forth in the previous amendment.

The rejection based upon Ganz is based upon an erroneous reading of the reference. Ganz clearly discloses using two separate catheters 57 and 57a. Catheter 57 is a right Judkins configuration (col. 5, line 68), while catheter 57a is a left Judkins configuration (col. 6, lines 58-59). Two additional catheters 11 and 11a are used with catheters 57 and 57a. Particularly catheters 11 and 11a are passed through the lumens of catheters 57 and 57a respectively. The distal portion of catheter 57 is relatively straight (see Figs. 10 and 11), and thus have no real relevance to the present invention. Additional catheters 11a and 57a have curved distal end segments—in fact they have the same curvature. This is to insure that catheter 11a is held **distally** with respect to catheter 57a against rotation. See col. 7, lines 27-41, which state:

“In addition, the advancing of the catheter 11a through the catheter 57a brings about the necessary cooperation between the bend sections 109 and 67a with the orientation bend sections 101 and 103, respectively, **to properly angularly orient the passage-seeking bend section 105 so that it will enter the artery 107.** It is believed that the orientation of the bend section 105 takes place as a result of orientation bend sections 101 and 103 resiliently seeking their natural or unstressed condition, and this they are allowed to do when they are within the associated bend sections 109 and 67a, respectively, of the catheter 57a. This

rotates the bend section 105 into the correct position so that the bend section 105 is angularly oriented **as it emerges** from the distal opening 65.” (Emphasis added).

This passage clearly reveals that any “fixing” or “holding” of the inner catheter 11a with respect to the outer catheter 57a occurs distally, rather than proximally as required by the present invention.

Ganz requires five catheters (11, 11a, 11b, 57, and 57a) to perform an intubation of the left and right coronary ostia. The present invention—with its unique capabilities—is able to intubate the same two ostia with **only two** elements: the inner curved (or curvable) catheter and the outer curved (or curvable) tube or sheath. Ganz is completely different from the present invention, and has no clue (or teaching) that the present invention is even possible. Ganz simply teaches away from the present invention. All the claims are allowable over Ganz for these reasons.

Finally, the rejection based upon Cho in view of Ueda and Takahashi is also without foundation. The distinction between Cho and the present invention is explained in detail in the previous amendment. Ueda and Takahashi do not add to the merits of the rejection. Preliminarily, where is there any motivation in this art to combine Cho with either reference, much less with both? This art simply does not recognize that the Cho device could be dramatically improved. Only the present invention recognizes this. Similarly, Ueda and Takahashi are silent as to the need or possibility that they or Cho could be improved by making the hypothetical combination suggested by the Examiner. The Examiner also makes the statement that the various ducts require out of plane shapes. But there is no showing using the references that such out of plane shapes are achieved in the manner required by the present claims. Out of plane shapes are known—it is



the unique method and apparatus for achieving them that forms the basis for the present claims. The Examiner has wholly failed to indicate how the presently cited references meet all the limitations of the present claims to achieve out of plane shapes. The present rejection should be withdrawn for all these reasons.

New claims 23-32 are allowable for the same reasons set forth above with respect to the existing claims. For example, claim 23 depends from claim 1 and is allowable along with that claim. It also provides for means for **proximally fixing** the distal end portion of the inner medical element in the second curve. This feature is not shown in the references, as discussed above.

Claim 24 depends from claim 19 and is allowable for essentially the same reasons as that claim. This claim also provides for **proximally fixing** the distal end of the combination catheter substantially out of the first plane.

Claim 25 depends from claim 1 and similarly provides for means for **proximally fixing** the inner medical element against translation and rotation with respect to the catheter tube. It is thus allowable for the same reasons as claim 1 and claims 23 and 24 above.

Claim 26 depends from claim 19 and is allowable for the same reason as that claim. It further requires **proximally fixing** the inner medical element **against translation and rotation** with respect to the catheter tube. As described above, these features are not found in the references.

Claim 27 is an independent claim directed to a combination catheter. This claim specifies a catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane. It also requires an inner medical element having a distal end portion adapted to be fixed in a second curve such that the distal end portion of the inner

medical element is disposed substantially out of the first plane. The claim also provides for means for **proximally fixing** the inner medical element **against translation and rotation** with respect to the catheter tube. It is, therefore, allowable for essentially the same reasons as claim 26.

Claim 28 is an independent method claim that includes forming out-of-plane shapes and **proximally fixing** the inner medical element **against translation and rotation** with respect to the catheter tube. As described above, these features are absent from the cited art.

Claim 29 is another new method claim that specifies (1) **forming the combination catheter into a first shape** in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element; (2) **proximally fixing** the inner medical element **against translation and rotation** with respect to the catheter tube while the distal end of the combination catheter is disposed substantially out of the first plane; (3) **forming the combination catheter into a second shape**, different from the first shape, in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element; and (4) **proximally fixing** the inner medical element against **translation and rotation** with respect to the catheter tube while the distal end of the combination catheter is disposed in the second shape. None of the references show such a method.

Claim 30 is an independent apparatus claim similar to claim 27, and is allowable for the same reasons as that claim. It specifically provides that the distal end portion of the inner medical element is fixed in a second curve defining a second plane, such that the second plane defined by the distal end portion of the inner medical element is disposed substantially out of the

first plane. It also provides for means for **proximally fixing** the inner medical element **against translation and rotation** with respect to the catheter tube while the distal end portion of the inner medical element is disposed substantially out of the first plane.

Claim 31 depends from claim 10 and requires that the second curve be disposed substantially out of the first plane as a result of rotating the inner medical element with respect to the catheter tube. The references do not show any such out-of-plane feature as defined by these claims.

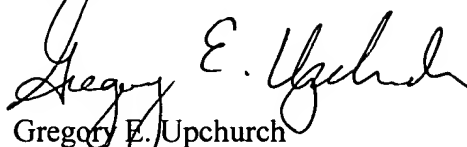
Claim 32 depends from claim 19 and provides that the forming step includes rotating the inner medical element with respect to the catheter tube. It is allowable for essentially the same reasons as claim 19 and claim 31.

Similarly, new claims 33 and 34 depend from claim 10. Claim 33 further specifies that the step of fixing includes **proximally fixing** the distal end of the combination catheter substantially **out of the first plane**. Claim 34 further specifies that the step of fixing includes **proximally fixing** the inner medical element **against translation and rotation** with respect to the catheter tube. As noted above, these features are absent from the prior art.

Models illustrating the various families of curves achievable with the present invention were sent to the Examiner in connection with the parent application. Such models will greatly facilitate understanding of the issues, as will the videotape supplied at the same time to the Examiner, demonstrating a computerized simulation of the use of the models. Models and the videotape are believed to be currently in the Examiner's possession, as a result of the prosecution of the parent case. Applicant respectfully requests the opportunity to interview this case for the purpose of demonstrating the models and showing the videotape.

Favorable reconsideration and a Notice of Allowability of the remaining claims is solicited.

Respectfully submitted,

A handwritten signature in cursive script, reading "Gregory E. Upchurch". The signature is written in dark ink and is positioned above the printed name and contact information.

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## Summary of Arguments from Prior Amendment

### Sylvanowicz Distinctions

- The distal end portion 62 of catheter tube 52 in Sylvanowicz is **straight** not curved.
- The curved portion of Sylvanowicz is not “fixed” as that term is used in the present application.
- The distal end of Sylvanowicz does not define a plane as required by the present claims.
- Neither the Fig. 12 nor the Fig. 14 configuration of Sylvanowicz would anticipate the present claim which requires an “out-of-plane” shape during medical use of the inner medical element or the catheter tube.
- The Examiner’s actions in one of the parent applications of the present application show that the out-of-plane feature is not inherent in Sylvanowicz.
- Since the distal end portion of the catheter tube in Sylvanowicz is straight, it is incapable of providing the surprising interaction of two curves which results in the inner element being thrown out of plane with respect to the outer catheter tube.
- An infinite number of planes pass through the longitudinal axis of the straight distal end portion 62 of the catheter tube in Sylvanowicz, and so in the Fig. 12 and Fig. 14 positions in Sylvanowicz and in all positions in between, the longitudinal axis of the distal end portion 54 of the inner element lies in one of those planes.
- There is no showing that the relevant portions in Sylvanowicz are necessarily in planes at significant angles with respect to each other, or that anyone in the art has ever recognized the presently claimed “out of plane” feature.

- Sylvanowicz clearly contemplates rotation and translation of the inner tube with respect to the outer. Apparatus that is designed to rotate and translate can hardly be said to be “fixed” against rotation and translation.
- The only curve in the outer catheter tube of the Sylvanowicz reference is disposed substantially farther from the distal end of the catheter tube than three times the radius of the curve of the inner element (which is the curve with the smaller radius of curvature).

### **Petruzzi Distinctions**

- Petruzzi has a straight distal portion of the outer tube whose longitudinal axis is in the same plane as the distal portion of a curved inner element 56.
- There is no indication the inner element 56 in Petruzzi will occupy any plane other than the one defined by the longitudinal axis of the outer tube.
- The drawings of Petruzzi, which hide the opening facing the ampulla of Vater, are totally consistent with a manipulation which result in the distal end, the window, and the guiding catheter of Petruzzi being “in plane”—not out-of-plane as required by these claims.
- An out-of-plane shape of the distal end in Petruzzi, as explained below, is unachievable since the distal end is straight, solid, and unbendable.
- With the apparatus of Petruzzi, the only way to direct the catheter to the ampulla of Vater is by seeing the ampulla straight on line of sight through the window.
- The Examiner’s theory—looking in one direction and catheterizing in another which you cannot see and do not know the location of—is impossible with the Petruzzi device.
- Nothing in Petruzzi comes close to hinting that these distal end portions of the two parts could be disposed “at a significant angle” with respect to each other. Instead, it appears that in Petruzzi these distal end portions are substantially planar.

- Petruzzi lacks any suggestion of the interaction of two curved elements which results in the surprising “out of plane” feature of the present invention.
- Petruzzi clearly does not show a curve in the outer element within the specified distance from the distal end of that outer element. In fact, the relevant distal portion of the outer element of Petruzzi is clearly straight, and no provision is disclosed by which the relevant distal portion could be bent.
- In the Petruzzi apparatus rotation of the inner element with respect to the outer tube would result in an apparatus that would not hit what it was aiming at. The motivation for making such an inoperative device is minimal, at best.

#### **Cho Distinctions**

- Cho has no disclosure of rotation of an inner curved distal portion with respect to an outer curved distal portion.
- The distal end of the outer tube of Cho is straight, which means that its longitudinal axis defines an infinite number of planes.
- The inner element of Cho, even if curved, always falls within one of these infinite number of planes. For example, no matter how the inner element in Cho is rotated, its distal end remains in the same plane as the distal end of the outer catheter tube.
- If the outer tube in Cho were curved in the manner specified by the present invention, Cho would be inoperable. A simple rotation of the inner element would not result in the intubation of the two passages illustrated in Cho. In fact, that operation would be impossible because the inner element would not longer be positioned correctly.
- Cho is directed to a different problem, and has no teaching whatsoever of the out-of-plane feature resulting from the presently claimed invention.

- The only motivation for modifying Cho in this manner is the hindsight provided by the present invention.

#### **D'Amelio Distinctions**

- D'Amelio et al. requires four (4) operating cables (pull-wires) 64 to manipulate the flexible end member 60 of a borescope 34 for inspecting a jet engine, and is therefore much more complicated than the presently claimed apparatus.
- If D'Amelio et al. were actually performing the presently claimed invention, only one of the pull-wires would be needed (as in the present application).
- There is nothing in D'Amelio et al. which would motivate one of ordinary skill in the art to make any modifications to the D'Amelio et al. apparatus whatsoever. The apparatus appears to adequately solve the problems at hand, and there are no hints of any deficiencies in D'Amelio et al.
- The claimed inventions are very different from D'Amelio et al. D'Amelio et al. is indifferent to the shapes formed by the apparatus since the D'Amelio device has direct information as to the direction in which the device is pointing. (The entire purpose of D'Amelio et al. is to point an optical inspection apparatus toward the area of interest.) Any duplication of the present invention, forming out-of-plane shapes, therefore, is not only accidental or unwitting, it would be purely unintentional.
- D'Amelio et al., unlike the present invention, is attempting to stay away from the walls of the object under examination, and specifically desires to stay in the center of the can of the jet engine being examined. The D'Amelio et al. invention is described in the context of relatively open spaces through which the examining device moves (see references in the table in the previous amendment to "relatively open spaces" from col. 2, lines 3-22,



for example), which is very different from the environment in which the present invention is used.

- Examination of Figs. 13-19 of D'Amelio et al. clearly reveals that the distal portions (as defined) are planar, not "out of plane".
- With respect to Fig. 19, D'Amelio et al. expressly teaches that "objective assembly 46 **must articulate in the same plane** as the guide member 36." Col. 8, lines 37-39.
- D'Amelio et al. does not teach out of plane shapes.
- D'Amelio et al. teaches longitudinal fixing only, and specifically teaches the desirability of **allowing the inner element to rotate freely with respect to the outer tube**. In fact, fixing the inner element against rotation would be directly contrary to the oft-stated and consistent intent of the disclosure of D'Amelio et al. to freely rotate to inspect the components of the jet engine.
- D'Amelio et al. teaches neither the structure for rotationally fixing, nor the step of rotationally fixing.